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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/979,533	03/08/2002	Alfred Jann	112843-035	5939

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BELL, BOYD & LLOYD, LLC
PO BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
MARX, IRENE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/979,533	JANN ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 23-24* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The application should be reviewed for errors. Error occurs, for example, in the repeated recitation of "pionate" at page 10 of the specification. Error also occurs in the spelling of "blook" at page 9, line 1.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/04 has been entered.

Claims 6 and 23-24 are being considered on the merits.

Claims 1-5 and 7-21 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is vague and indefinite in that it is at least ambiguous whether the nutritional composition as a whole is administered in an amount of 2 g per day to about 15 g per day or whether this is the amount of dextran provided in the composition. The claim appears incomplete in that the amount of the sole active ingredient, i.e., dextran, is not set forth with any particularity.

Claims 6 and 23-24 are vague, indefinite and confusing in that the nature of the "insulin sensitivity" is not clearly set forth in the instant context. Is this a method of treatment of a medical condition or merely an optional improvement in insulin sensitivity? Moreover, the extent of "increase" of "insulin sensitivity" is not set forth with any particularity. Is it 0.0001%,

0.1%, 1%, 10%, 50%?. No clear indication in this regard is found in the instant specification, particularly with respect to effects or effectiveness of enteral administration as now claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation in claim 6 of "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day". The recitation in the specification at page 1, lines 30-33 broadly discloses enteral administration for increasing insulin sensitivity in a mammal, but only mentions a nutritional composition which contains dextran. No indication is provided regarding molecular weight or administration protocol.

Insertion of the limitation "having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus of "enteral administration" which would show possession of the concept of the use of "dextran having a molecular weight above about 500,000 and that is administered enterally in an amount from about 2g per day to about 15g per day" for the purpose of increasing insulin sensititivy. The exemplified use of dextran is oral administration and for a purpose different from the claim designated purpose. Thus, this is not sufficient support for the new genus of "enterally administering dextran having a molecular weight above about 500,000 in an amount from about 2g per day to about 15g per day". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If

it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2 g per day to about 15 g per day" is considered to be the insertion of new matter for the above reasons.

This recitation differs substantially from the invention as claimed.

Therefore, this material constitutes new matter and should be deleted.

Claims 6 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a process of "increasing insulin sensitivity in a mammal" by a process comprising "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2g per day to about 15g per day" . However, the written disclosure does not disclose the amount of dextran suitable to be administered enterally for the claimed purpose. The broad statement at page 4, lines 4-6 does not indicate that this amount is to be provided enterally and how absorption through the intestine is to be achieved. No clear guidance is provided regarding the preparation and administration of suitable nutritional preparations containing the required amount of dextran to be provided enterally. The only dextran preparations provided are in oral form wherein 3-5 volunteers are provided "Dextran T2000" of undisclosed molecular weight. The type of preparation administered is not set forth with any particularity. The only result monitored was the effect of propionic acid in feces upon oral administration. Administration is not enteral. The written disclosure suggests that propionic acid concentration in feces increases upon oral administration of dextran. However, there is nothing on the record regarding a nexus or correlation between enteral administration of the recited dextran of high molecular weight in the amounts now claimed and any increase in insulin sensitivity. It is noteworthy that oral consumption of dextran T2000 induced no relevant changes of blood formula, investigated blood proteins or blood plasma enzymes. How is "increase in insulin sensitivity" monitored and on

whom? The effects of "enterally administering a nutritional composition comprising dextran having a molecular weight above about 500,000 and that is administered in an amount from about 2 g per day to about 15 g per day" are not addressed in the present written disclosure. There is no clear indication on the record regarding the administration protocol, form or dosages required to achieve the touted effect of "increasing insulin sensitivity" for enteral administration of dextran having a molecular weight above about 500,000 in an amount from about 2g per day to about 15g per day as claimed. Moreover, the effects of added polysaccharides and lipids in enteral nutritional compositions cannot be readily assessed. Also there is insufficient guidance in the written disclosure regarding the making of suitable enteral nutritional compositions as claimed for the desired purpose or how these compositions are to be enterally administered.

Therefore, the claims fail to comply with the enablement requirement, since the claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The art rejections are withdrawn in view of applicant's amendments. The rejections will be reinstated as appropriate upon removal of the new matter introduced by the instant amendment.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx

Irene Marx
Primary Examiner
Art Unit 1651